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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-D-0429]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance on Meetings with Industry and Investigators on the Research and Development of Tobacco Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0731. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Guidance on Meetings with Industry and Investigators on the Research and Development of

Tobacco Products--

OMB Control Number 0910-0731--Extension

The Family Smoking Prevention and Tobacco Control Act (Pub. L. 111-31) offers tobacco product manufacturers several pathways to obtain an order from FDA to authorize the marketing of a new tobacco product before it may be introduced or delivered into interstate commerce. To provide assistance with these pathways to market products, FDA will meet with tobacco product manufacturers, importers, researchers, and investigators (or their representatives) when appropriate. This guidance is intended to assist persons who seek meetings with FDA relating to their research to inform the regulation of tobacco products, or to support the development or marketing of tobacco products. The guidance has been revised to provide clarity.

In the guidance, the Agency discusses, among other things:

- What information FDA recommends persons include in a meeting request;
- How and when to submit a request; and
- What information FDA recommends persons submit prior to a meeting.

This guidance describes two collections of information: (1) The submission of a meeting request containing certain information and (2) the submission of an information package in advance of the meeting. The purpose of this proposed information collection is to allow FDA to conduct meetings with tobacco manufacturers, importers, researchers, and investigators in an

effective and efficient manner. FDA issued this guidance as a level 2 guidance consistent with FDA's good guidance practices regulations (21 CFR 10.115).

Meeting Requests: The guidance sets forth FDA's recommendations for materials to be included in a request for a meeting with FDA to discuss the research and development of tobacco products. In the guidance, FDA recommends that the following information be included in the meeting request:

1. Product name and FDA-assigned Submission Tracking Number (if applicable);
2. Product category (e.g., cigarettes, smokeless tobacco) (if applicable);
3. Product use (indicate for consumer use or for further manufacturing);
4. Contact information for the authorized point of contact for the company requesting the meeting;
5. The topic of the meeting being requested (e.g., a new tobacco product application, an application for permission to market an MRTP, or investigational use of a new tobacco product);
6. A brief statement of the purpose of the meeting, which could include a discussion of the types of studies or data to be discussed at the meeting, the general nature of the primary questions to be asked, and where the meeting fits in the overall product development plans;
7. A preliminary list of the specific objectives/outcomes expected from the meeting;
8. A preliminary proposed agenda, including an estimate of the time needed and a designated speaker for each agenda item;
9. A preliminary list of specific questions, grouped by discipline (e.g., chemistry, clinical, nonclinical);

10. A list of all individuals who will attend the meeting on behalf of the tobacco product manufacturer, importer, researcher, or investigator, including titles and responsibilities;
11. The date on which the meeting information package will be received by FDA; and
12. Suggested format of the meeting, e.g., conference call, in-person meeting at FDA offices, video conference, or written response, and suggested dates and times for the meeting. Meetings are usually scheduled for 1 hour.

This information will be used by the Agency to: (1) Determine the utility of the meeting, (2) identify Agency staff necessary to discuss proposed agenda items, and (3) schedule the meeting.

Meeting Information Packages: An individual submitting a meeting information package to FDA in advance of a meeting should provide summary information relevant to the product and supplementary information pertaining to any issue raised by the individual or FDA to be discussed at the meeting. As stated in the guidance, FDA recommends that meeting information packages generally include updates of information that was submitted with the meeting request and, as applicable:

1. Product composition and design data summary;
2. Manufacturing and process control data summary;
3. Nonclinical data summary;
4. Clinical data summary;
5. Behavioral and product use data summary;
6. User and nonuser perception data summary; and

7. Investigational plans for studies and surveillance of the tobacco product, including a summary of proposed study protocols containing the following information (as applicable):
- a. Study objective(s);
 - b. Study hypotheses;
 - c. Study design;
 - d. Study population (inclusion/exclusion criteria, comparison group(s);
 - e. Human subject protection information, including Institutional Review Board information;
 - f. Primary and secondary endpoints (definition and success criteria);
 - g. Sample size calculation;
 - h. Data collection procedures;
 - i. Duration of follow up and baseline and follow up assessments, and
 - j. Data analysis plan(s).

The purpose of the information package is to provide Agency staff the opportunity to adequately prepare for the meeting, including the review of relevant data concerning the product. In the Agency's experience, reviewing such information is critical to achieving a productive meeting. For the information that was previously submitted in the meeting request, the information package should provide updated information that reflects the most current and accurate information available.

Description of Respondents: The respondents to this collection of information are manufacturers, importers, researchers, and investigators of tobacco products who seek to meet with FDA to discuss their plans regarding the development or marketing of a tobacco product.

In the Federal Register of September 17, 2015 (80 FR 55855), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden¹

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Meeting Requests					
Combining and Sending Meeting Request Letters for Manufacturers, Importers, and Researchers	67	1	67	10	670
Meeting Information Packages					
Combining and Submitting Meeting Information Packages for Manufacturers, Importers, and Researchers	67	1	67	18	1,206
Total					1,876

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA's estimate of the number of respondents for meeting requests in table 1 of this document is based on the number of meeting requests to be received over the next 3 years.

In the next 3 years of this collection, FDA estimates that 67 preapplication meetings will be requested. The number is not expected to change, as the public is more experienced in submitting applications for substantial equivalence, requests for nonsubstantial equivalence, etc.

Thus, FDA estimates the number of manufacturers, importers, researchers, and investigators who are expected to submit meeting requests in table 1 of this document to be 67 (50 year-1 requests + 100 year-2 requests + 50 year-3 requests ÷ 3). The hours per response, which is the estimated number of hours that a respondent would spend preparing the information recommended by this guidance to be submitted with a meeting request, is estimated to be

approximately 10 hours each, and the total burden hours for meeting requests are expected to be 670 hours (10 hours preparation/mailing \times 67 average respondents per year). Based on FDA's experience, the Agency expects it will take respondents this amount of time to prepare, gather, copy, and submit brief statements about the product and a description of the purpose and details of the meeting.

FDA's estimate of the number of respondents for compiling meeting information packages in table 1 of this document is based on 67 respondents each preparing copies of their information package and submitting them to FDA, for a total of 1,206 hours annually. The hours per response, which is the estimated number of hours that a respondent would spend preparing the information package as recommended by the guidance, is estimated to be approximately 18 hours per information package. Based on FDA's experience, the Agency expects that it will take respondents 1,206 hours of time (67 respondents \times 18 hours) to gather, copy, and submit brief statements about the product, a description of the details of the anticipated meeting, and data and information that generally would already have been generated for the planned research and/or product development.

The total number of burden hours for this collection of information is 1,876 hours (670 hours to prepare and submit meeting requests and 1,206 hours to prepare and submit information packages).

Dated: January 29, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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